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EXAMINER	
KALINOWSKI, ALEXANDER G	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/923,385	MICHELSON ET AL.
	Examiner	Art Unit
	Alexander Kalinowski	3626

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-15 and 129-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15 and 129-151* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2-15 and 129-151 are presented for examination.

Response to Arguments

2. In view of the supplemental appeal brief filed on 11/5/2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

3. Upon a review of provisional Application No. 60/178,634, the Examiner has determined that several limitations claimed by Applicant are not supported in the '634 application. For example, the '034 does not enable the feature of "automatically presenting questionnaires " or "presenting questionnaires ...". Therefore, features that were not disclosed or enabled in the '034 application will be given a priority date of the earliest enabling disclosure which is PCT/US01/02936 (1/29/2001).

4. Applicant's arguments with respect to claims 2-15 and 129-151 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 includes the limitation of "other off-line sources". This is indefinite in that Applicant has listed specific offline sources in the claim limitation yet uses the phrase "other off-line sources". For purposes of applying prior art, the Examiner will not consider the phrase "other off-line sources".

7. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner cannot determine the scope of the claim limitation of "the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database". Is the person or caregiver required to present genetic sequence information when the person or caregiver registers with the database in step a) ? If so, then the claim contains a missing step since this information is not included in the claimed registration step. Or is the disease condition of interest that is input by the person or caregiver during the registration process of step a) associated with a particular genetic sequence

information? Or are there clinical trials related to specific studies relating genetic sequence information to a specific diseases that relate to the patient's or caregiver's disease condition of interest as submitted during the registration step a)? For purposes of applying prior art, the Examiner, as best understood by a reading of the specification, will interpret this limitation as matching patients with a clinical study that is attempting to relate genetic sequence information to a disease.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2, 4-14 and 130-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, Gary, "System makes it easier to link patients to clinical trials"(hereinafter Baldwin" in view of information available at the website of CenterWatch (hereinafter CenterWatch) and Knight, Pub. No. 2002/0099570.

As per claim 2. Baldwin discloses a method for recruiting a person to participate as a subject in a clinical study (i.e. link patients to clinical trial)(title and abstract), comprising the steps of.

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database (i.e. AOR Securenet is a secure externet ... patient

information is entered online...)(page 2), wherein the registration information includes at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators ...)(page 2-3);

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information (see entire article);

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators...)(pages 2-3);

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician... open to select users. Clinicians, drug companies and administrators ...)(pages 2-3);

Baldwin does not explicitly disclose

wherein the registration information includes at least a geographic location of the person.

However, CenterWatch discloses wherein the registration information includes at least a geographic location of the person (i.e. Patient Notification Service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the registration information includes at least a geographic

location of the person and automatically presenting a questionnaire associated with the given clinical study to the person or caregiver as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

Baldwin and CenterWatch do not explicitly disclose

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d).

(f) storing answers submitted by the person or caregiver in the database .

However, Knight discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) (i.e. trial specific questions)(Fig. 1, Fig. 8, and paragraph 70). Knight also discloses storing answers submitted by the person or caregiver in the database (i.e. patient database)(paragraphs 114-125). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 4. Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study.

However, Knight discloses wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study ((i.e. trial specific questions)(Fig. 1, Fig. 8, and paragraph 70). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention

to include wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 5, Baldwin and CenterWatch do not explicitly disclose The method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (page 2).

However, Knight discloses wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (paragraphs 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 6, Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a

personal library associated with the person or caregiver on the web site (Fig. 10 and Fig. 11).

As per claim 7, Baldwin discloses The method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (page 2).

As to claim 8, Baldwin, CenterWatch, and Knight do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send requested notice information via mail. The motivation for delivering notice by regular mail is for the convenience of the requestor. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the notice provided in step (d) is sent by regular mail to the person or caregiver within the Baldwin, CenterWatch and Knight combination for the motivation stated above.

As to claim 9, Baldwin, CenterWatch and Knight do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send notice information by telephone to a requestor. The motivation for delivering notice by telephone is for the convenience of the requestor. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the notice provided in step (d) is communicated by telephone to the person or caregiver within the Baldwin, CenterWatch and Knight combination for the motivation stated above.

As per claim 10, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

However, Baldwin does disclose wherein a determination is made to provide the person or caregiver with the notice in step (c) as discussed previously above. CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study (CenterWatch Patient Notification service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include notice of clinical studies in accordance with a geographic location of the given clinical study as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 11. Baldwin discloses The method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given

clinical study (i.e. fuzzy matches. The Examiner interprets this feature to read on clinical trials that the person or caregiver does not match)(page 2).

As per claim 12, Baldwin discloses The method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (page 2).

As per claim 13, Baldwin does not explicitly disclose The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

However, Baldwin discloses wherein a determination is made to provide the person or caregiver with the notice in step (c). CenterWatch discloses providing a list of clinical study(ies) in accordance with a geographic location of a clinical study as discussed previously above (the Examiner interprets the geographic determination limitation to include the geographic location of the clinical trial the investigator is associated with). It would have been obvious to one of ordinary skill at the time of Applicant's invention to include the geographic location matching of CenterWatch with the determination step of Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 14. Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

However, the Examiner takes official notice that it was well known in the electronic arts to provide information by telephone, mail or fax. The motivation was to provide the customer with customer preferred delivery methods particularly with highly sensitive information. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features above within Baldwin, CenterWatch and Knight for the motivation stated above.

As to claim 130, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-examination questionnaire

However, Knight discloses said questionnaire is a pre-examination questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 131, Baldwin and CenterWatch do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a screening questionnaire

However, Knight discloses said pre-examination questionnaire is a screening questionnaire . It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said pre-examination questionnaire is a

screening questionnaire as disclosed by Knight within Baldwin, CenterWatch, and TVisions for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 132, Baldwin and CenterWatch do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a pre-screening questionnaire

However, Knight discloses said pre-examination questionnaire is a pre-screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 133, Baldwin and CenterWatch and do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-screening questionnaire

However, Knight discloses said questionnaire is a pre-screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 134, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is a screening questionnaire.

However, Knight discloses said questionnaire is a screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 135, Baldwin and CenterWatch do not explicitly disclose the method of claim 134, wherein said screening questionnaire is protocol specific.

However, Knight discloses said screening questionnaire is protocol specific (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 136, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is designed for screening for clinically appropriate persons..

However, Knight discloses said questionnaire is designed for screening for clinically appropriate persons (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said

questionnaire is designed for screening for clinically appropriate persons as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 137, Baldwin, CenterWatch and TVisions do not explicitly disclose the method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria

However, Knight discloses said questionnaire requests information regarding inclusion/exclusion criteria (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said questionnaire requests information regarding inclusion/exclusion criteria as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 138, the claim is similar in scope to claim 131 and is rejected on the same basis.

As to claim 139 and 140, the claims are similar in scope to claim 138 and are rejected on the same basis.

As to claims 141-148, the claims are similar in scope to claims 130-137 and are rejected on the same basis.

As to claims 149-151, the claims are similar in scope to claim 138 and are rejected on the same basis.

10. Claims 3 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Knight as applied to claim 2 above, and further in view of "TVisions wins Top Web Externet Award; Recognized for Creative, Life-Saving Site" (hereinafter TVisions).

As per claim 3, Baldwin, CenterWatch, and Knight do not explicitly disclose The method of claim 2, further comprising the step of:

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

However, TVisions discloses accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) (i.e. additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by TVisions within Baldwin, CenterWatch and Knight for the motivation of alerting physicians within seconds of possible matches of their patients with available or new clinical trials (page 2, second paragraph).

As per claim 129, Baldwin, CenterWatch and Knight discloses method for recruiting a person to participate as a subject in a clinical study as explained in claim 2 above.

Baldwin and CenterWatch and Knight do not explicitly disclose

(e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site.

However, TVisions allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site (i.e. additions and updates are to the patient profile database ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by TVisions for the motivation of alerting physicians within seconds of possible matches of their patients with available clinical trials and new clinical trials (page 2, second paragraph).

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Knight as applied to claim 2 above, and further in view of Larkin, Marilynn, "Physicians accelerate onto the Internet" (hereinafter Larkin).

As per claim 15, Baldwin and CenterWatch do not explicitly disclose The method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

However, Baldwin discloses wherein the step of automatically determining. Larking discloses clinical studies directed to particular genetic sequences and using online recruitment (page 2). It would have been obvious to one of ordinary skill in the

art at the time of Applicant's invention to include the online patient recruitment of clinical studies for genetic studies within the Baldwin, CenterWatch and Knight method for the motivation of speeding up patient recruitment (i.e. within 6 months of the site's inauguration, 127 eligible woman ... By contrast, it took 4 years to recruit 395 volunteers with traditional methods ...)(see abstract and page 2)

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. "TVisions builds a site for oncology researchers and their clinical trials" discloses an Internet web site that matches patients with clinical trials.

b. "Object Products Inc." discloses clinical trial patient recruitment software with full Internet capability.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

Alexander Kalinowski

Primary Examiner

Art Unit 3626

2/22/2004